



1129187

Food and Drug Administration
Washington DC 20204

WARNING LETTER
OFL 01-99

CORRECTION
VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 28, 1999

Mr. David Langer
Vice President
Langers Juice Co.
16195 Stephens Street
City of Industry, California 91745

Dear Mr. Langer:

FDA has reviewed labels for several of your juice products and find that these products bear claims that misbrand the products under section 403 of the Federal Food, Drug, and Cosmetic Act (the act) and that may render the products drugs under section 201(g) of the act.

Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are drugs under section 201(g)(1)(B) of the act. Accordingly, a statement on a food label or in its labeling that claims the food is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease makes the product bearing the statement a drug under section 201(g)(1)(B) of the act. Under section 403(r) of the act, however, food labels and labeling may bear authorized health claims. A health claim is a claim characterizing the relationship between a substance and a disease. FDA authorizes health claims following the submission of a petition and promulgation of a regulation. In addition, the act authorizes health claims based on authoritative statements through a notification procedure set out in section 403(r)(3)(C) of the act. A food bearing a health claim that is not authorized by regulation or the act misbrands the product under section 403(r) of the act.

In addition, articles, other than a food, that are intended to affect the structure or function of the body of man are drugs under section 201(g)(1)(C) of the act. Accordingly, a food label or labeling may bear statements about a substance's effect on the structure or function of the body. Such effects on the structure or function of the body must be achieved through nutritive value and the statement about the effects may not claim to diagnose, mitigate, treat, cure, or prevent disease. A structure-function claim on a food that is not achieved through nutritive value renders the product a drug under section 201(g)(1)(C) of the act.

Food labels and labeling may also bear authorized nutrient content claims under section 403(r) of the act. A nutrient content claim is a claim characterizing the level of a nutrient in a food.

Like health claims, FDA authorizes nutrient content claims following the submission of a petition and promulgation of a regulation and the act authorizes nutrient content claims based on authoritative statements through a notification procedure set out in section 403(r)(2)(G) of the act. A food bearing a nutrient content claim that has not been authorized by regulation or the act misbrands the product under section 403(r) of the act.

1. White Grape [Juice from concentrate] with Essential Antioxidants Vitamin C & Grape Seed Extract

This product is misbranded within the meaning of section 403(r)(1)(B) of the act in that the label bears unauthorized health claims. The claims include "Protect your heart as you quench your thirst," "Flavonoids... inside grape skins and seeds... help lower bad cholesterol, keep arteries open and decrease cancer risk...", and a claim that compares the effect on the body of your product to "the heart-protecting strength in a glass of red wine." Because the claims on this product are not authorized as health claims by regulation or by the act, the claims misbrand the product.

This product is also misbranded within the meaning of section 403(r)(1)(A) of the act in that the label bears unauthorized nutrient content claims. The claims include "just as many flavonoids as purple grape juice" and "two glasses equal the...strength in a glass of red wine." Such claims imply that both foods are good sources of flavonoids. Since there is no daily value established for flavonoids these claims can not be authorized. Because the claims on this product are not authorized as nutrient content claims by regulation or by the act, the claims misbrand the product.

This product is also misbranded within the meaning of section 403(a) of the act in that the label bears the claim "with Essential Antioxidants....GRAPE SEED EXTRACT...", which suggests that grape seed extract is an essential nutrient. Because grape seed extract is not an essential nutrient, the claim misbrands the juice.

2. Grape Juice with Essential Antioxidants Vitamin C & Grape Seed Extract

This product is misbranded within the meaning of section 403(r)(1)(B) of the act in that the label bears unauthorized health claims. The claims include "Protect your heart as you quench your thirst," "heart-healthy benefits of red wine," and "Flavonoids...inside grape skins and seeds...help lower bad cholesterol, keep arteries open and decrease the risk of cancer...." Because the claims on this product are not authorized as health claims by regulation or by the act, the claims misbrand the product.

This product is also misbranded within the meaning of section 403(r)(1)(A) of the act in that the label bears unauthorized nutrient content claims. The claims include the statement "...twice the flavonoids of regular purple grape juice" and "just as many as a glass of red wine." Such claims imply that both foods are good sources of flavonoids. Since there is no daily value established for flavonoids these claim can not be authorized. Because the claims on this product are not authorized as nutrient content claims by

regulation or by the act, the claims misbrand the product.

This product is also misbranded within the meaning of section 403(a) of the act in that the label bears the claim "with Essential Antioxidants...GRAPE SEED EXTRACT" which suggests that grape seed extract is an essential nutrient. Because grape seed extract is not an essential nutrient, the claim misbrands the juice.

3. Cranberry Grape 100 with Essential Antioxidants Vitamins A, C, & E, Grape Seed Extract and Co Enzyme Q10 and Magnesium

This product is misbranded within the meaning of section 403(r)(1)(B) of the act in that the label bears unauthorized health claims. The claims include "Antioxidants help protect your immune system from free radicals, unstable molecules that contribute to disease and aging," "The flavonoids in purple grapes...help lower bad cholesterol," "the heart-protecting power of a glass of red wine," and "We added...magnesium, which helps prevent certain cancers...." Because the claims on this product are not authorized as health claims by regulation or by the act, the claims misbrand the product.

This product is also misbranded within the meaning of section 403(r)(1)(A) of the act in that the label bears unauthorized nutrient content claims. The claims include "Each glass...equals the...power of a glass of red wine" and "We added co enzyme Q-10...." Since there is no daily value established for flavonoids or co-enzyme Q-10 these claims can not be authorized. Because the claims are not authorized as nutrient content claims by regulation or by the act, the claims misbrand the product.

This product is also misbranded within the meaning of section 403(a) of the act in that the label bears the claim "It's the grape seed extract and other essential antioxidants" which suggests that grape seed extract is an essential nutrient. Because grape seed extract is not an essential nutrient, the claim misbrands the juice. In addition, the claim "NO...FLAVORS...ADDED" misbrands the product under section 403(a) of the act because the ingredient statement declares "natural flavors."

4. Raspberry Cranberry 100 with Essential Antioxidants Vitamins A, C, & E, Ginkgo Biloba, Ginseng, and Potassium

This product is misbranded within the meaning of section 403(r)(1)(B) of the act in that the label bears unauthorized health claims. The claims include "Antioxidants help protect your immune system from free radicals, highly unstable molecules that contribute to disease and aging" and "A diet rich in these vitamins has also been associated with decreased cancer risk." Because the claims on this product are not authorized as health claims by regulation or by the act, the claims misbrand the product.

This product is also misbranded within the meaning of section 403(r)(1)(A) of the act in that the label claims that the product contains “added ginkgo biloba” and “Plus, ginseng (American and Siberian).” Since there is no daily value established for ginkgo biloba and ginseng these claims can not be authorized. Because these statements are not authorized as nutrient content claims by regulation or by the act, the statements misbrand the product.

This product is also misbranded within the meaning of section 403(a) of the act in that the label bears the claim “NO...FLAVORS...ADDED” while the ingredient statement declares “Natural Flavors.”

5. Cranberry 100 With Essential Antioxidants Vitamins A, C, & E and Calcium Added

This product is misbranded within the meaning of section 403(r)(1)(B) of the act in that it bears an unauthorized health claim. The claim is “Antioxidants help protect your immune system, and a diet rich in these vitamins is associated with decreased risks of several types of cancer.” Because this claim is not authorized by regulation or by the act as a health claim, this claim misbrands the product.

6. Coldbuster 100 Essential antioxidants, Vitamins A and C, with Echinacea & Zinc

The product label bears statements that suggest that the product is intended to treat, prevent, cure, or mitigate disease, namely the common cold. These claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act. In addition to the product’s name, “Coldbuster,” the claims suggesting that this product is intended for use as a drug include “ColdBuster 100 is just what the doctor ordered. At the first sign of a cold, pour yourself a glass of this delicious, immune-boosting juice. We’ve loaded it with nature’s best cold fighters: echinacea, zinc and vitamins A & C. [E]chinacea is a plant known for its healing, anti-viral properties; zinc shortens the duration of a cold, and Vitamins A&C help you fight infections and strengthen your immune system. Together, they can deliver your cold a knockout punch...So when you feel the sniffles or a sore throat coming on,...Cold Buster 100 is the perfect prescription.” Because these statements suggest that the product is intended to treat, cure, mitigate, or prevent the common cold, they suggest that this product is subject to regulation under the drug provisions of the act.

The above violations are not meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to assure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

In addition to the claims identified above, we are also concerned about other statements on the labels of your products that describe the effects of certain substances on the body. For example, claims on your products include suggestions that certain ingredients provide “brain-boosting

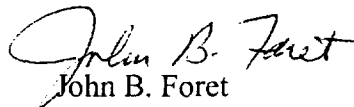
power to enhance memory and circulation” and “increase energy and longevity.” As discussed at the beginning of this letter, such claims must be in the form of an appropriate claim to affect the structure or function of the body and the claimed effect must be achieved through nutritive value.

We also note that under the act, any ingredient intentionally added to a conventional food like these juices must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or approved causes a food to be adulterated under section 402(a)(2)(C) of the act and cannot be legally marketed in the U.S. We note that ingredients such as echinacea, grape seed extract, and ginkgo biloba are listed on the labels of several of these juices. FDA has not issued a food additive regulation authorizing the use of these ingredients in food. Additionally, we are not aware of a basis for concluding that these ingredients are GRAS for use in conventional food.

Please notify the FDA Los Angeles District office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your letter should also include your basis for concluding that the claims on your product and the ingredients you use meet the requirements as outlined above. Copies of revised labels for the products should also be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to the Food and Drug Administration, Los Angeles District, 19900 MacArthur Blvd, Suite 300, Irvine, CA 92612, attn: Mr. Thomas Sawyer.

Sincerely yours,



John B. Foret

Director

Division of Programs
and Enforcement Policy
Office of Food Labeling
Center for Food Safety
and Applied Nutrition